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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,036	09/29/2003	Jeff R. Justis	MSDI-137/PC977.00	2570
52196 7590 11/15/2007 KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 11/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,036

Applicant(s)

JUSTIS, JEFF R.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-14, 16, 46-58, 60-64, 67-72 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-12, 16, 46-50, 53-64, 67-71 and 74 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 51, 52 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to applicant's amendment received on 10/15/2007.

Allowable Subject Matter

2. The indicated allowability of claims 8-12, 16, 46-50, 53-57, 59, 67-71, and 74 is withdrawn in view of the newly discovered reference(s) to Ilizarov (U.S. Patent 5,067,954). Rejections based on the newly cited reference(s) follow.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, ...wherein said guide instrument includes a mounting assembly coupled with said guide member, said mounting assembly being removably mounted to said pair of anchor extensions and said mounting assembly is positionable about said proximal ends of said pair of anchor extensions and clampable thereto and said guide instrument including a coupling member rotatably coupled to a clamp assembly adjacent said proximal end of one of the anchor extensions, said coupling member extending from said rotatable connection with said clamp assembly to a coupling portion, said guide member being rotatably coupled to said coupling portion of said coupling member (claims 16, 58, and 74) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. As shown in Figures 11 and 12 of the application, the guide instrument includes a mounting assembly (221) that is clamped to the proximal ends of the anchor extensions. The guide instrument further includes a coupling member (239) rotatably coupled to the mounting assembly not an additional clamping assembly as written in the claims. The

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examiner is unable to find support for an additional clamping assembly in the specification (page 13 lines 21-25 to page 15 lines 1-16) or in the drawings (Figures 11 and 12) pertaining to this embodiment of the invention.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 16, 58-64, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 16, 58, and 64 state,... wherein said guide instrument includes a mounting assembly coupled with said guide member, said mounting assembly being removably mounted to said pair of anchor extensions and said mounting assembly is positionable about said proximal ends of said pair of anchor extensions and clampable thereto and said guide instrument including a coupling member rotatably coupled to a clamp assembly adjacent said proximal end of one of the anchor extensions, said coupling member extending from said rotatable connection with said clamp assembly to a coupling portion, said guide member being rotatably coupled to said coupling portion of said coupling member. The examiner believes the mounting assembly is the clamping assembly that the coupling member is coupled to. The written description (page 13 lines 21-25 to page 15 lines 1-16) do not disclose the invention comprising a clamping assembly in addition to the mounting assembly nor do the drawings pertaining to the specific embodiment of the invention (Figures 11 and 12) show the invention comprising an additional clamping assembly. Therefore, the examiner believes that claims 16, 58-64, and 74 fail to comply with the written description requirement. The claims will be interpreted as written for examination purposes.

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6, 9-12, 46-50, 53-57, and 67-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aferzon (U.S. Publication 2005/0234449) in view of Illizarov (U.S. Patent 5,067,954).

Regarding claims 1, 46, and 67, Aferzon discloses a device comprising a pair of anchor extensions capable of being engaged with an animal subject and a guide instrument capable of being mounted adjacent the proximal ends of the pair of anchor extensions (see Figure 1 below). The anchor extensions include a proximal end and a distal end, wherein the distal ends form an alignment axis when engaged with an animal subject. The guide instrument includes a guide member and a mounting assembly coupled to the guide member. The guide member defines a guide axis that intersects the alignment axis when mounted to the anchor extensions. The guide member is capable of being rotated around the proximal ends of the anchor extension while mounted thereto in order to reposition the guide axis relative to the anchor extension while maintaining the guide axis in an intersecting relationship with the alignment axis. Regarding claims 2 and 53, Aferzon discloses a device further comprising an inserter that a proximal portion pivotally mounted adjacent the proximal ends of the anchor extensions and a distal portion extending transversely to the proximal portion, wherein

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the distal portion is moveable about the proximal ends of the anchor extensions by pivoting the proximal portion relative thereto. Regarding claims 3 and 54, Aferzon discloses a device further comprising a connecting element releasably engaging the distal portion of the inserter, wherein the connecting element is capable of being positioned along the alignment axis with the inserter. Regarding claims 4 and 55, Aferzon discloses a device wherein the connecting element is a rod. Regarding claims 5 and 56, Aferzon discloses a device further comprising a pair of anchors each including a distal portion and a proximal receiver portion. The distal portion is capable of engaging a bony segment. The proximal receiver portion defines a passageway capable of being aligned along the alignment axis, wherein the anchor extensions are capable of being mounted to the proximal receiver portions of the anchors. Regarding claims 6 and 57, Aferzon discloses a device wherein the anchors are multi-axial screws. Aferzon fails to disclose the device wherein the mounting assembly further comprises a mounting member and a coupling member (claims 1, 46 and 67). Ilizarov teaches a device comprising a mounting assembly (see Figure 4 of the reference) comprising a mounting member (31) and a coupling member (34) in order to allow the surgeon to add or remove mounting assemblies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Aferzon wherein the mounting assembly further includes a mounting member and a coupling member in view of Ilizarov in order to allow the surgeon to add or remove mounting assemblies.

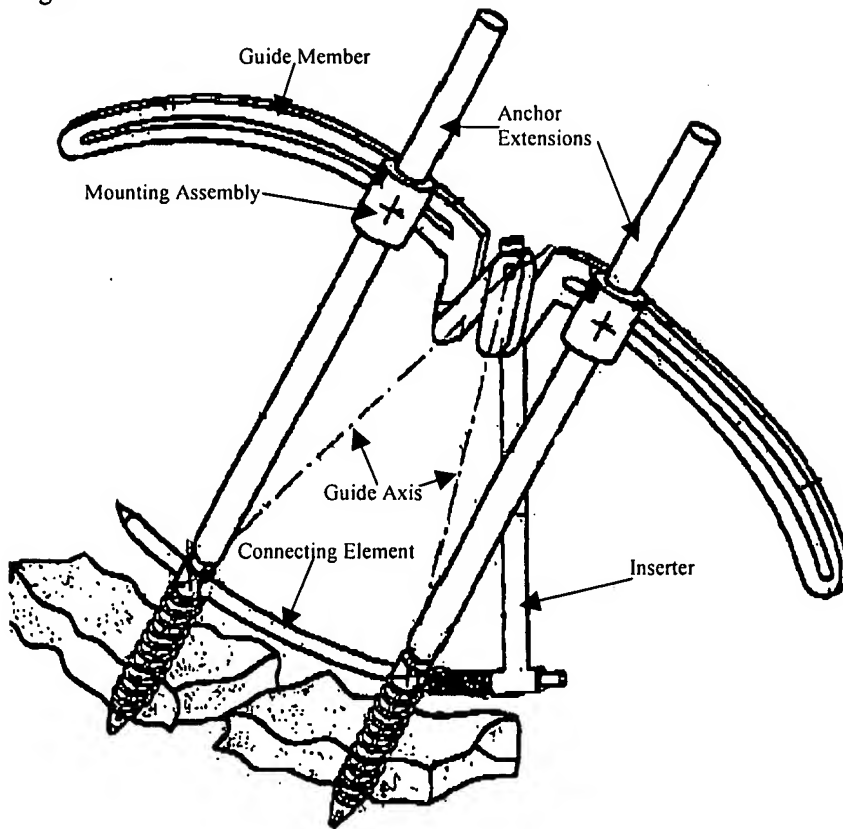
Further regarding claim 1, the combination of Aferzon and Ilizarov disclose a device wherein the coupling member of the mounting assembly is capable of being

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rotationally mounted to and extending proximally from said mounting member and the mounting member being capable of being removably mounted between the pair of anchor extensions along a mounting axis. Regarding claims 9, 47, and 68, the combination of Aferzon and Ilizarov disclose a device wherein the coupling member is removably mounted to the mounting member. Regarding claims 10, 48, and 69, the combination of Aferzon and Ilizarov disclose a device wherein the guide member is pivotally coupled to the coupling member about a hinge axis offset from the mounting axis. The examiner believes that the guide members (46A and 46B) are indirectly pivotally coupled to the coupling members about a hinge axis that is located at the pivot point P. Since the tracks of the guide members are arc-shaped and the guide members are capable of being positioned by the connected links 32A and 42A or 32B and 42B the movement caused by the connected links on the guide members is being interpreted by the examiner as being a rotational or pivoting movement relative to the coupling member, wherein the guide member is indirectly coupled to the coupling member through a mounting pin (33). Regarding claims 11, 49, and 70, the combination of Aferzon and Ilizarov disclose a device wherein the guide member includes a bore at pivot point P that extends diametrically along the guide axis. Regarding claims 12, 50, and 71, the combination of Aferzon and Ilizarov disclose a device wherein the coupling member is capable of being rotationally and removably coupled to the mounting member with a mounting pin (33) extending through a bore of the mounting member, wherein the bore extends along the mounting axis. The examiner is interpreting the mounting axis to extend along the longitudinal axis of the mounting pin.

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Figure 1



Allowable Subject Matter

8. Claims 13, 14, 51, 52, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER